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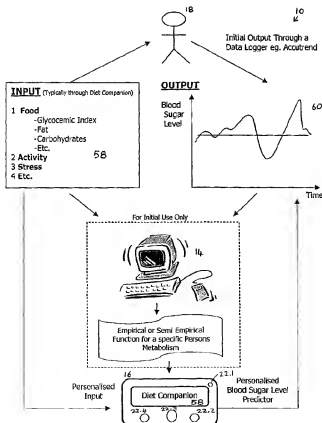
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[Continued on next page]

(54) Title: A DIETARY SYSTEM: "BLOOD SUGAR PREDICTING SYSTEM"



(57) Abstract: The invention provides a dietary system (10) that includes a storage means with a database of human factors and programs for receiving user data on human factors and then predicting a selected characteristic of blood (typically blood sugar level) of a user (18) using the database, user data and prediction models. Bloodsugar is the predominant characteristic to be predicted. There is also provided a portable computer-connectable-dietary-device. This device includes storage means (26, 30, 31, 34) for receiving and storing data including the prediction models on a selected blood characteristic as a function of human factors, input means for receiving human factor data from user, processor for generating prediction models and a display for displaying predicted blood characteristics. Human factor may be selected from list of "food intake", "activity level" and "stress level" and any human factor that may affect the selected characteristic. The method predicts selected blood characteristic as a function of human factor.

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*For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.*

**A DIETARY SYSTEM: "BLOOD SUGAR PREDICTING SYSTEM"**

THIS INVENTION relates to a dietary system. It also relates to a dietary device and to method of predicting a selected characteristic of blood of a user.

For the purposes of this specification, the application of this invention to  
5 predict the blood sugar level of a person, e.g. a diabetic, should be predominantly, but not exclusively, borne in mind. Diabetes is caused by a person's inability to produce insulin which maintains the person's blood sugar level relatively constant. A diabetic's inability to produce sufficient insulin can result in fluctuations in blood sugar level and, accordingly, insulin is injected into the body after a blood sugar test has been conducted  
10 i.e. to remedy a potentially dangerous fluctuation that has arisen. For example, if blood sugar levels have gone too high, kidney failure or the like may occur thereby shortening the diabetic's life. However, if the blood sugar level has gone too low, brain damage can result.

According to the invention there is provided a dietary system, which  
15 includes

storage means including a data base of reference human factors and a program for a computer operable to receive user data on the human factors and predict a selected characteristic of blood of the user dependent upon user data and measured blood characteristics thereby to generate a prediction model; and

20 a portable dietary device connectable to the computer, the device including  
storage means for receiving and storing the prediction model;  
input means for receiving input human factor data from the user;  
processor means for interrogating the prediction model to generate a  
predicted blood characteristic dependent upon the input human factor data; and  
25 display means for displaying the predicted blood characteristic.

Further in accordance with the invention, there is provided a portable dietary device which includes

storage means for receiving and storing a data base which includes a prediction model on a selected blood characteristic as a function of a human factor;  
input means for receiving input human factor data from a user;  
processor means for interrogating the prediction model to generate a predicted blood characteristic dependent upon the input human factor data; and  
display means for displaying the predicted blood characteristic.

Further in accordance with the invention, there is provided a method of predicting a selected characteristic of blood of a user, the method including  
providing a data base which includes a prediction model on the selected characteristic as a function of a human factor;  
obtaining input human factor data from a user;  
interrogating the data base to obtain the selected characteristic as a function of the input human factor data; and  
displaying the selected characteristic.

The human factor may be selected from the group consisting of food intake, activity level and stress level. It is, however, to be appreciated that any human factor which may affect the selected characteristic may be included.

The selected characteristic is typically the blood sugar level of a user such as a diabetic. Accordingly, the method may be used to predict the blood sugar level as a function of time dependent upon past and future human factors. The display means may then provide a graphical prediction of the person's blood sugar level for a plurality of hours taking proposed future human factors into account. Dependent upon the predicted blood sugar level, the diabetic may then alter or adapt his or her intended human factors e.g. eat a particular foodstuff, exercise more or less, or the like. Accordingly, the invention extends to a blood sugar prediction system including the system and method as hereinbefore described.

Providing a data base may be iteratively generated by the user recording human factor data over a time period and, during the time period, periodically conducting

an actual blood sugar analysis. For example, in order to configure the device, the user may enter or identify in the device the combination of past and/or present human factors and use a conventional Accutrend™ device to obtain measured blood sugar level data. The program of the system may then include functionality to import the actual blood sugar analysis, which would be date and/or time stamped by the Accutrend™ device, and generate and/or update the prediction model.

The dietary device may include a communications interface, e.g. an RS 232 interface or the like, for communicating with the computer running the program. Accordingly, when the user feeds in human factor data during configuration of the device, the device may date and time stamp the data. When the data is fed into the computer, the prediction means within the program may generate the prediction model from the measured blood sugar level data and the human factor data.

The input means and display means of the device preferably operate in a menu driven fashion. Accordingly, the device may include appropriate software and the display means is typically an LCD display. The input means typically includes a scroll key, an enter key, and the like.

The method may include prompting a user for selected human factor data in a menu driven fashion. For example, the display may provide the following three human factors, "activity level", "stress level", and "food intake" which are selectable in a menu driven fashion. If the user selects "activity level" or "stress level", the following options may be provided, "high", "medium", or "low". The "activity level" may include the following further options, "select duration", "select specific type", or the like.

The "food intake" selection may allow selection of specific foodstuffs in predefined quantities. In this regard, the entire contents of PCT Patent Application No. PCT/IB00/00343 is hereby incorporated by reference.

The invention is now described, by way of example, with reference to the accompanying diagrammatic drawings.

In the drawings,

Figure 1 shows a schematic representation of a dietary system in accordance with the invention;

Figure 2 shows a block diagram of the system of Figure 1;

5 Figure 3 shows a more detailed schematic diagram of the system of Figure 1;

Figure 4 shows a schematic representation of functions performed by a dietary device of the system of Figure 1 in various stages of operation of the dietary device;

Figure 5 shows a schematic diagram of functions performed by a user of the dietary device in various stages of operation of the dietary device;

10 Figure 6 shows a schematic representation of various functions performed by a personal computer of the system of Figure 1 in various stages of operation of the dietary device; and

Figure 7 shows a schematic representation of functions performed by a blood monitoring device of the system of Figure 1.

15 Referring to the drawings, reference numeral 10 generally indicates a dietary system in accordance with the invention. The system 10 includes a blood sugar monitoring device 12, a PC 14, a dietary device 16, also in accordance with the invention, and a patient or user 18. The user 18 is typically a diabetic and the system 10, as described in more detail below, may be used to predict a blood sugar level of the user  
20 18 dependent on various human factors such as food intake, physical activity level, stress level, or the like.

Referring in particular to Figure 2 of the drawings, the dietary device 16 includes a user interface 20 comprising an on/off button 22.1, an enter button 22.2, a scroll button 22.3, and a back button 22.4. The device 16 further includes an RS232  
25 serial connection 24, storage means or memory 26 in which a blood sugar prediction model (as described in more detail below) is stored, a processor 28 which defines a device manager and controls operation of the device 16, further memory 30, 32 in which stress level recorded data and activity level data, respectively, are stored; and storage means or memory 34 in which a food intake data file is stored and in which foodstuffs  
30 consumed by the user are recorded.

The system 10 includes storage means in the form of a CD Rom or the like and a program for controlling operation of the PC 14. In particular, the CD Rom includes a comprehensive food data base 36, an activity data base 38, prediction means 40 for creating and updating the prediction model, a management module 42, a serial port communication interface 44, and a graphical user interface 46.

The graphical user interface 46 and the user interface 20 of the device 16 allow a user to select and input selected data into the device 16 as shown by lines 48 and 50. Thus, the user 18 may, via the user interface 20, identify a particular stress level as shown at block 52, identify a particular physical activity at block 54, select and identify particular foodstuffs which have or are to be consumed during a given time period as shown at block 56, and via an LCD display 58 (see Figures 1 and 3) read the predicted blood sugar level as shown at block 60. The user interface 20 and the display 58 in combination with the processor 28 allow the user 18 selectively to feed data into the device 16 in a menu driven fashion (see Figure 3). The predicted blood sugar level predicted by the device 16 is shown in the form of a graph 60 (see Figure 3).

In order for a diabetic to use the device 16 to predict his or her blood sugar level dependent upon various human factors such as food intake, physical activity, stress level or the like, a prediction model for the particular user must be generated. Thus, the use of the system 10 may be divided into three different stages. In stage 1, various data bases of the device 16 are configured by feeding in data sourced from both the dietary device 16 and the blood sugar monitoring device 12. As described in more detail below, the software run on the PC 14 takes the user 18 through a step-by-step process to build a personalised food data base stored in the memory 34, a physical activity data base stored in the memory 32, and a stress data base stored in the memory 30. Generation of these data bases is accomplished by an iterative process and, during use of the device 16, further data may be fed into the PC 14, thereby to update and enhance the aforementioned data bases. Updating of the data bases stored in the memory 26, 30, 32, 34 by the PC 14 is achieved by the RS232 serial connection 24 and the serial port communication interface 44 as shown by line 62.

In the second stage of operation, data to generate the prediction model is acquired. In particular, during a particular time period, the user 18 identifies and feeds in

human factor data relating to stress level, physical activities during the period, food intake during the period and so on, into the device 16 via the user interface 20. As the data is entered into the device 16 it is date and time stamped. During the predetermined time period, the user also obtains measured values of his or her blood sugar level by means of the blood sugar monitoring device 12. The device 12 is typically an Accutrend™ device which has an ability to record time and date stamp data as shown at block 64 form a blood sugar analysis on a sample as shown at block 66.

The device 12 has a human interface 68 which includes a sensor and a graphical user interface and, in addition, a device manager is operable to control operation of the device 12. The device 12 further includes a serial connection 70 for connecting the device 12 to the PC 14 as shown by line 72. Thus, the human factors during the time period are identified and actual measured blood sugar levels are obtained and fed into the PC 14 which then, by means of the prediction means 40, generates a prediction model which provides a blood sugar level output as a function of the various human factors. It is to be appreciated that any number of iterations in which the stress level, physical activity, food intake or the like of the user 18 is monitored and actual blood sugar measurements by means of the device 12 may be carried out, thereby to enhance the accuracy of the prediction model.

In stage 3 of operation of the device 16 in which the prediction model has been downloaded into the device 16 via the serial interface, the device 16 may then be used to predict a blood sugar level as a function of time (see graph 60 in Figure 3) dependent upon both past and future human factors. In particular, the human factors that have taken place during a particular time window as well as future human factors, are used to predict the blood sugar level of the user 18. For example, the user 18 may predict that strenuous exercise and the intake of specific food types are going to take place at given times during the next couple of hours and feed this data into the device 16 via the user interface 20. The processor 28 may then interrogate the data bases stored in the memory 26, 30, 32, 34 and predict a blood sugar level of the user 18. The user 18 may then inspect the graph 60 and dependant upon its form, modify his or her human factors, for example, food intake, so that a more suitable graph is generated. Thus, if the user 18 expects to do strenuous physical activity during the course of the day, the user 18 may then select or plan his or her diet accordingly so as to achieve a desired



blood sugar level during the course of the day. Typically, the user 18 is a diabetic who can then plan their entire day insofar as food intake, physical activity or the like is concerned, so as to achieve a relatively flat blood sugar level graph. It is to be appreciated that the device 12 may be used to randomly monitor the blood sugar level and, if necessary, the procedures followed in stage 1 may be repeated.

In order to assist the user 18 in operating the system 10, system instructions are included in the CD Rom provided with the system 10. For example, during stage 1, the instructions may include :

1. Install the software on the PC.
2. Follow on screen instructions to set up the food and activity data bases.
3. Upload the data bases into the dietary device 16.

In stage 2, the instructions may be as follows :

1. Eat food and perform activities under certain stress levels.
2. Record the stress level, diet and activities on the dietary device.
3. Measure the blood sugar level with the electronic sugar level monitor.
4. Repeat the above many times to acquire enough data for deriving a model.
5. Download both the stress/diet/activity and the blood sugar recorded files to the PC.
6. Let the PC derive a suitable prediction model for the input data.
7. Upload the prediction model to the dietary device.
8. If more data is needed, repeat either stages 1 or 2 or both.

The system instructions for stage 3 may be as follows :

1. Plan to eat certain food and perform certain activities under certain stresses for the whole day.
2. Enter these parameters in the dietary device.
3. Get a predicted blood sugar level from the dietary device output.

4. Alter diet and activity planning to predict a suitable blood sugar level for the given day.
5. Eat the food and perform the activity.
6. If the actual blood sugar level differs from the predicted level, repeat stages 1 or 2 or both.

5

Referring in particular to Figures 4 to 7 of the drawings, the functionality carried out in the various stages by the dietary device 16, the user 18, the PC 14 and the blood sugar monitoring device 12 are shown.

In stage 1, the dietary device 16 obtains configured data files from the PC 14 as shown by block 74 whereafter the memory 34, 32 and 30 are updated as shown in blocks 76, 78, 80, respectively. In stage 2 of operation of the system 10, the dietary device 16 is used to record various human factors taking place during a given time period. In particular, the device 16 is used to record the various foodstuffs which have been eaten as shown at block 82, determine what physical actions have been done as shown at block 84, and record the particular stress levels experienced by the user 18 as shown at block 86. During this stage, the memory 34, 32, 30 is updated with relevant data as shown in blocks 88, 90, 92. This process is repeated iteratively until enough data has been accumulated, whereafter the data is downloaded into the PC 14 as shown at block 94.

As described above, during stage 3, the dietary device 16 is used to predict a blood sugar level of the user 18. Accordingly, as shown in Figure 4, the user 18 identifies relevant foodstuffs which are to be eaten as shown at block 96, identifies particular activities that are to take place as shown at block 98, and selects particular stress levels s shown at block 100. The processor 28 then processes the information in accordance with the prediction model as shown at block 102, and provides a graphical representation of the predicted blood sugar level of the user 18 (see block 104) over a given time period (see graph 60 in Figure 3). If the user 18 is satisfied that the graph 60 is suitable, then the device 16 may then be used at a later date to update the human factors. However, if the user 18 is not satisfied with the predicted blood sugar level content, the steps in stage 3 may be iteratively repeated to obtain a modified or new predicted blood sugar level. For example, the user 18 may alter the nature and quantity

of the food intake so as to change the predicted blood sugar level content. In this regard, the contents of PCT Patent Application No. PCT/IB00/00343 in the name of Mathews, Edward Henry and Mathews, Comelia entitled "A dietary system" is hereby incorporated by reference.

5 Referring in particular to Figure 5 of the drawings, the procedural steps and functionality of the user 18 during the three stages is shown graphically. In stage 1, during which data is accumulated to generate the prediction model, the user 18 selects certain foodstuffs for a diet as shown at block 106, chooses or identifies various physical  
10 activities which are to take place during a given period, as shown at block 108, and the user 18 identifies or chooses various stress levels using the user interface 20 as shown at block 110. This process is repeated iteratively and, when the user 18 is satisfied with the selection, the relevant data files from the PC 14 are uploaded into the dietary device  
15 16 as shown at block 112. During this procedure, the user selects in blocks 106, 108, 110 data from predefined data which is provided on the CD Rom provided with the system 10.

During stage 2 in which the prediction model is generated, the user 18, by means of the user interface 20, identifies the foodstuff intake as shown at block 114, or feeds in particular physical activities which have been performed (as shown at block  
20 116) into the dietary device as shown at blocks 118, 120. Further, the dietary device 16 is updated by the user to identify various stress levels (see block 122) which the user 18 has been exposed to. As a result of the aforementioned human factors, the blood sugar level of the person 18 changes as shown at block 124 and the blood sugar monitoring device 12 is used to obtain a measured reading of the blood sugar level of the user 18  
25 as shown at block 126. Thereafter, data from both the blood sugar monitoring device 12 and the dietary device 16 is fed into the PC 14 as shown at block 128.

During stage 3 of operation of the system 10, the dietary device 16 is used to predict the user 18's blood sugar level. In particular, the user 18 enters in planned food intake (see block 130), planned physical activities (see block 132), and  
30 estimated stress levels (see block 134) into the dietary device 16 via the user interface 20. The device 16 is thus updated with expected activities or human factors as shown at block 136 and the processor 28 provides a predicted blood sugar level output as shown

at block 138. If the user 18 is not satisfied with the predicted blood sugar level output, the planned food intake, physical activities, stress levels (as shown in blocks 130, 132 and 134) may be adjusted until an acceptable graph 60 is produced. Thereafter, the user 12 would then eat the planned food as shown at block 140, do the planned physical  
5 activities 142, or try to maintain the stress level as shown at block 144.

As mentioned above, the blood sugar monitoring device 12 may be a conventional Accutrend™ device which obtains a measured blood sugar level as shown at block 146 (see Figure 7), which updates a recorded data file as shown at block 148 and, if sufficient data is provided, the data is downloaded into the PC 14 as shown at  
10 block 150. If sufficient measured data is not provided, the process is repeated iteratively as shown by line 152.

In Figure 6 of the drawings, operation of the PC 14 in the various stages of operation of the system 10 is provided. Initially, in stage 1, the user 18 chooses the popular foods as shown in block 154 in an iterative manner as shown by line 156  
15 whereafter, particular activities from a master data base are chosen in a similar fashion as shown at block 158. Thereafter, the data bases are uploaded in the dietary device 16 as shown at block 160. In stage 2, the data is uploaded from the blood sugar monitoring device 12 and from the dietary device 16 as shown at blocks 162, 164, respectively, whereafter the prediction means generates a suitable prediction model based on the  
20 input data as shown at block 166. The PC 14 then uploads the prediction model into the dietary device 16 as shown at block 168. In stage 3, the PC 14 may be used to reconfigure the human factors as shown at block 170, and update the data in the device 16 as shown at block 172.

It is believed that the invention, as illustrated, provides a relatively simple  
25 dietary system 10 including a dietary device 16 which allows a diabetic to predict blood sugar levels as a function of human factors. Accordingly, the diabetic may plan physical activity, foodstuff intake, or the like, so that an acceptable blood sugar level over a period of time is achieved. Accordingly, the likelihood of potentially dangerous fluctuations in blood sugar levels may be reduced. Further, as the user may plan his or  
30 her diet and activity level, the amount of injected insulin required by the user can be reduced thereby increasing the life expectancy of the user.

**CLAIMS**

1. A dietary system including amongst others a dietary device and dietary method to predict a selected characteristic of blood of a user. The predominant but not exclusive application of the dietary system is to predict the blood sugar level of a person.
- 5 2. A system as claimed in claim 1 includes storage means (including database of human factors) and a program for a computer operable to receive user data on the human factors and predict a selected characteristic of blood of the user dependent upon the user data and measured blood characteristics thereby to generate a prediction model
- 10 3. A system as claimed in claim 1 also includes a portable computer connectable device including storage means for receiving and storing the prediction model; input means for receiving input human factor data from the user; processor means for interrogating the prediction model to generate a predicted blood characteristic dependent upon the input human factor data; and display means for displaying the predicted blood characteristic.
- 15 4. The system as claimed in claim 1 and 3 also provides a portable dietary device and a computer graphical user interface which includes storage means for receiving and storing a data base which includes a prediction model on a selected blood characteristic as a function of a human factor; input means for receiving input human factor data from a user; processor means for interrogating the prediction model to generate a predicted
- 20 blood characteristic dependent upon the input human factor data; and display means for displaying the predicted blood characteristic.

5. The system as claimed in claims 1,2, 3 and 4 also provides for a method of predicting a selected characteristic of blood of a user. The method includes providing a data base which includes a prediction model on the selected characteristic as a function of a human factor; obtaining input human factor data from a user; interrogating the data base to obtain the selected characteristic as a function of the input human factor data; and displaying the selected blood characteristic.

6. The human factor used by the method claimed in claim 5 may be selected from the following three human factors, "food intake", "activity level" and "stress level" in a menu driven fashion.

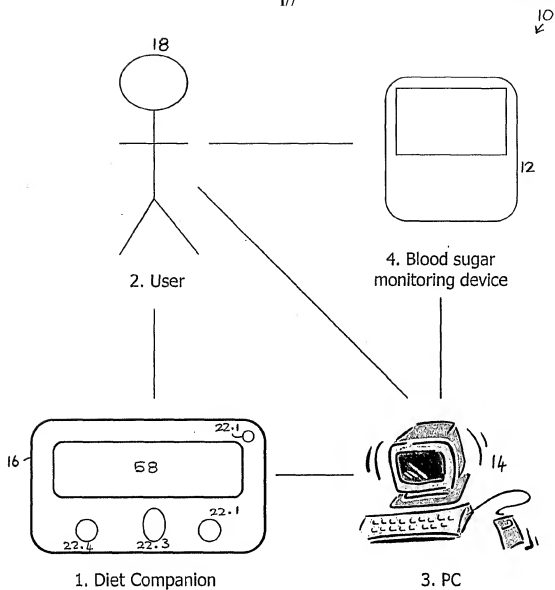
7. The human factor of "activity level" selected by user as stated in claim 6 will provide user three options of intensity: "high", "medium" or "low". Further options such as duration and specific type of exercise or activity are also provided for.

8. The human factor of "stress level" selected by user as stated in claim 6 will provide user three options of stress levels: "high", "medium" or "low".

9. The human factor of "food intake" selected by user as stated in claim 6 will provide user with a list of main food categories. Upon selection of a category a list of food subcategories are provided. Upon selection the user can then select a specific type of food. The entire contents of PCT Patent Application No. PCT/IB00/00343 is hereby incorporated by reference. The user will then specify the quantity of the food selected.

11. A new dietary system , substantially as herein described and illustrated

12. A new method of operation of a dietary device to predict blood characteristics, substantially as herein described and illustrated.

**FIGURE 1**



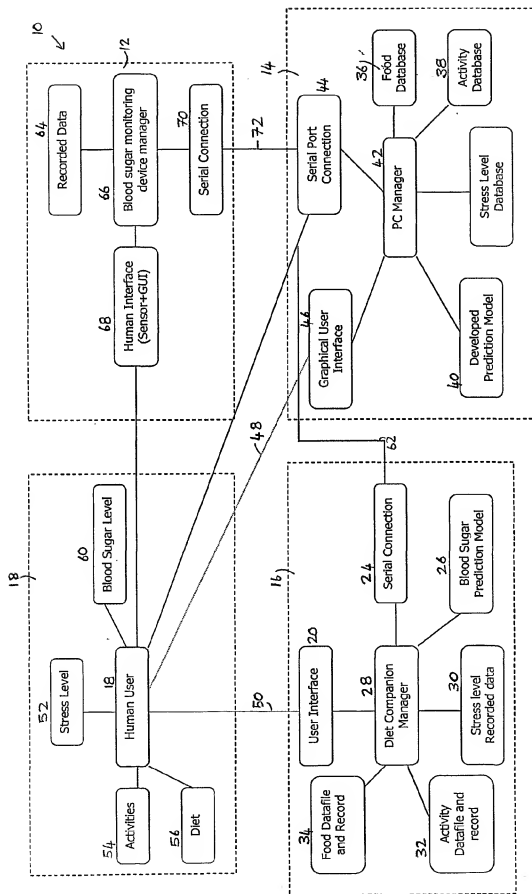


Figure 2

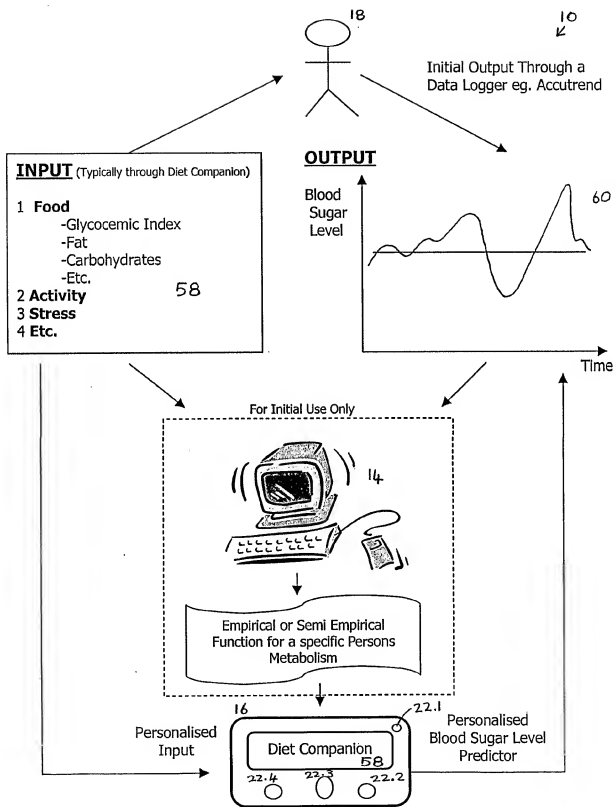


FIGURE 3

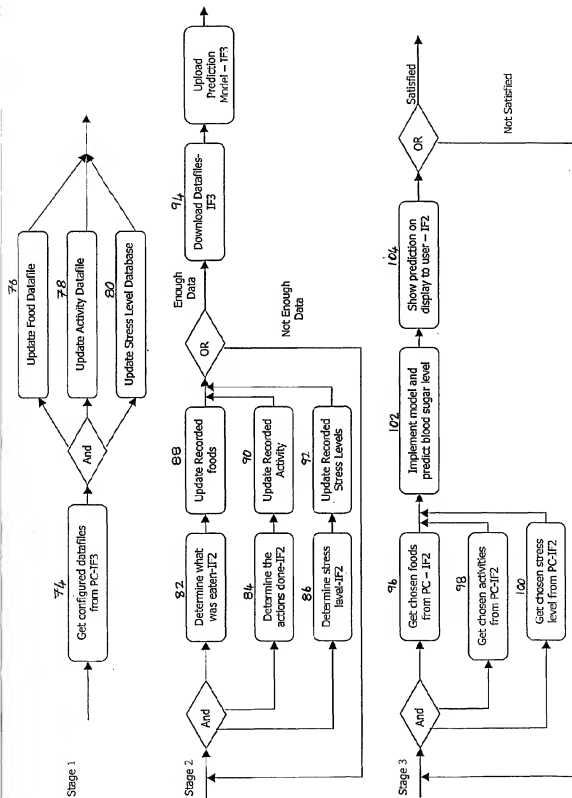


Figure 4

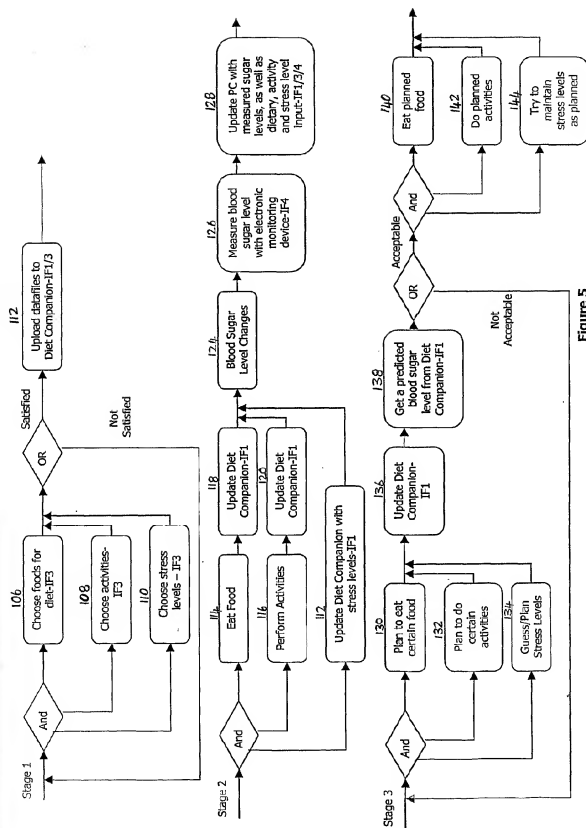


Figure 5

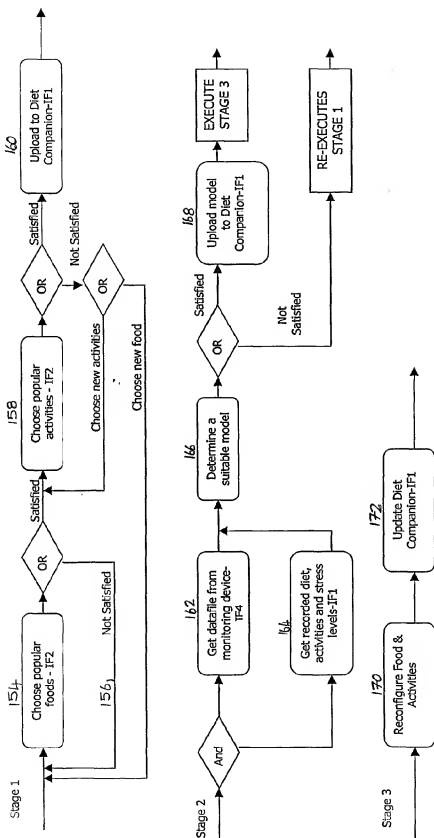


Figure 6

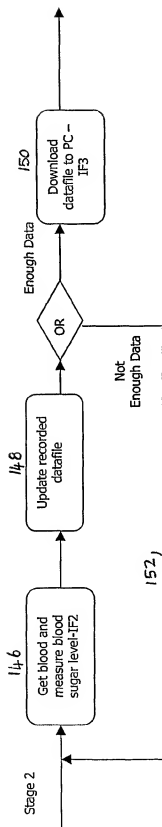


Figure 7

## INTERNATIONAL SEARCH REPORT

Internat. Application No.

PCT/LA 01/00201

A. CLASSIFICATION OF SUBJECT MATTER  
IPC 7 A61B5/00 G06F15/02

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61B G06F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 822 715 A ( D. R. L. WORTHINGTON ET AL ) 13 October 1998 (1998-10-13)	1-5, 11, 12
Y	column 4, line 3 -column 7, line 46	6-9
X	US 5 956 501 A ( S. J. BROWN ) 21 September 1999 (1999-09-21)	1-5, 11, 12
Y	column 3, line 62 -column 6, line 35	6-9
X	US 5 971 922 A ( S. ARITA ET AL ) 26 October 1999 (1999-10-26)	1-5, 11, 12
Y	column 1, line 40 -column 2, line 4 column 7, line 65 -column 9, line 34	6-9
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☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

2 July 2002

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11/07/2002

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## INTERNATIONAL SEARCH REPORT

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 08, 30 June 1999 (1999-06-30) & JP 11 056822 A (OMRON CORP), 2 March 1999 (1999-03-02)	1-5, 11, 12
Y	the whole document	6-9
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